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EXAMINER	
PORTER, RACHEL L	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,546	WHITSON, DEBI	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-14 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-14 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 9/21/05. Claims 1-7,9-11,13,14,17-21 are pending.

Oath/Declaration

2. The objection to the oath/declaration is hereby withdrawn due to the new declaration filed 9/21/05.

Claim Rejections - 35 USC § 112

3. The rejection of claims 7, 12-13, and 15-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby withdrawn due to the amendment filed 9/21/05.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4,5-6,11,14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites, "wherein the...questionnaire includes questions concerning the systems making up the human body...and is accomplished by a member of the clinical staff." It is unclear to the Examiner what how the phrase "accomplished by a member of

the clinical staff" is intended to modify the claim language. In particular, it is unclear whether the phrase means that the questionnaire given to the patient by a member of the staff, whether the staff fills in questionnaire for the patient, or whether the staff member drafts the questions of the questionnaire. For the purpose of applying the Examiner interprets this phrase to mean that a questionnaire is given to the patient by a member of the staff, and will apply art accordingly.

Claim 11 inherits the deficiencies of claim 4 through dependency, and is therefore also rejected.

Claim 5 recites the limitation "the scanner" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "a scanner", but instead refers to "a scanning type machine."

Similarly, claim 6 recites the limitation "from the scanner" in line 5. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "a scanner", but instead refers to "a scanning type machine." A similar analysis may be applied to claim 14, which also inherits the deficiencies of claim 6 through dependency and is also rejected

Claim 17 recites "the process of claim 8..." which has been cancelled. As such, the current claim dependency of claim 17 is unclear and it is also unclear which additional limitations the present claim incorporates through dependency. For the purpose of applying art, the Examiner will interpret the claim as being dependent from claim 10, which recites a computer.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1,3-5,9,11, 18-19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraftson et al (USPN 6,151,581-hereinafter Kraftson).

[claim 1] Kraftson discloses a process of allowing a patient to have limited input access to their electronic medical record, the method comprising of the steps of:

a) providing the patient with a machine readable questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)

b) interfacing a machine readable card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

c) arranging the data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's medical record; (col. 6, line 5-10; col. 7, lines 3-10)

d) sending the formatted data to an assigned location for importing into the patient's medical record. (col. 6, lines 10-18; col. 7, lines 43-53; col. 9, lines 37-49; col. 13, lines 30-40)

[claim 3] Kraftson teaches a process further comprising the step of forming a basic patient medical record by the patient in providing the information by written responses on the questionnaire. (col. 6, lines 41-46; col. 6, line 58-col 7, line 2)

[claim 4] Kraftson teaches a process wherein the machine-readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Figures 2A-C; 3A-C; Figure 13—see 112, 2nd rejection—Receptionist/staff helps provide patient questionnaire.)

[claim 5] Kraftson teaches a process wherein the step of interfacing the machine-readable card with the scanning type machine is accomplished by a member of the clinical staff. (col. 6, lines 1-10; col. 7, lines 3-10; col. 20, lines 5-8, lines 43-69 (e.g. Clinical staff member receives E-PDS and downloads the information patient information by connecting to the host device—see 112, 2nd rejection))

[claim 9] Kraftson teaches a process further comprising a step of receiving the formatted data with an interface engine (col. 7, lines 3-11;col. 12, lines 63-col. 13,

line 5; col. 13, line 7-12) and sending it to the database containing the patient's electronic medical record. (col. 7, lines 3-11; col. 13, lines 7-40)

[claim 11] Kraftson teaches a process wherein the machine-readable questionnaire is a paper answer sheet comprised of questions with designated areas for patient responses. (Figures 2A-C, col. 7, lines 3-11)

[claim 18] Kraftson discloses a method of supplementing a medical record with information submitted by a patient, the method comprising the steps of:

- receiving from the patient a machine-readable printed form containing information about a health status of the patient; (Figures 2A-2C, 3A-3C,13; col. 5, line 65-col. 6, line 3; col. 11, lines 43-58; col. 14, lines 28-67)
- electronically scanning the printed form to convert the information to machine processable data and communicate the data to a computer; (Figures 1 and 4; col. 7, lines 3-10)
- formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record that is personal to the patient; (col. 7, lines 6-10;col. 9, lines 32-49; col. 13, lines 59-61)
- communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record; and (Figure 4; col. 13, lines 6-25; 57-59; col. 14, lines 31-35, 58-67)

- presenting the information to a physician as part of the patient's personal electronic medical record. (col. 13, lines 41-51)

[claim 19] Kraftson discloses a method, further comprising the steps of:

- mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.)
- presenting the patient's electronic medical record to the physician, including the information from the printed form, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (col. 13, lines 6-51—patient information in PDMA is gathered from MRS or E-PDS surveys)

[claim 21] Kraftson discloses a method further comprising the steps of:

- mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.)
- presenting the patient's electronic medical record to the physician, including the information from the printed form, prior to the visit to inform the physician of the patient's health status. (col. 13, lines 6-51—patient information in PDMA is gathered from MRS or E-PDS surveys)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraftson as applied to claim 1 above, and further in view of Oyama et al (USPN 5,496,175).

[claims 2 and 10] Kraftson teaches a system/method of gathering and entering patient data into a patient database using professional staff members, (col. 7, lines 3-11) but does not expressly disclose inputting information using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering and input of questionnaire/survey data occurs using PC's with keyboards (col. 6, lines 21-36) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

[claim 17] Kraftson teaches a process wherein the computer processor is a standard PC (col. 8, lines 60-63; col. 19, lines 21-25). Kraftson does not expressly

disclose the specifications of the computer. However, Applicant provides no explanation in the specification as to why the recited specifications (32 MB of hard drive space and a processor capable of operating at 100 MHz) provide an advantage over other processor speeds and memory requirements. Moreover, it is respectfully submitted that at the time of the applicant's invention, a hard drive with at least 32 MB of memory and a processor with at least a 100 MHz processor were old and well known in the computer arts. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to include a computer with at least 32 MB of hard drive memory and at least a 100 MHz processor speed in the system of Kraftson and Oyama in combination with the motivation of making the method available to medical practices and individuals with limited computer resources.

10. Claims 6-7 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraftson as applied to claim 1 above, and further in view of Official Notice.

[claims 6-7 and 13-14]

Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3) and converting the obtained information into a data stream (col. 6, line 5-10; col. 7, lines 3-10), but does not expressly disclose the specific formats that are accommodated by the system. However, it is noted that HL7, ANSI, and ASTM are well known in

the art for establishing transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson to accommodate HL7, ANSI or ASTM protocol standards. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

11. Claims 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraftson in view of Johnson (USPN 5,664,109), and in further view of Evans (USPN 5,924,074).

[claim 20] Kraftson discloses a method supplementing a medical record with information submitted by a patient, the method comprising the steps of:

- receiving from the patient, prior to a visit with a physician (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.), a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms; (Figures 2A-2C, 3A-3C,13; col. 5, line 65-col. 6, line 3; col. 11, lines 43-58; col. 14, lines 28-67)
- electronically scanning the printed form to convert the information to machine-processable data and to communicate the data to a computer; (Figures 1 and 4; col. 7, lines 3-10)

- formatting the machine-processable data with the computer, wherein data includes the information from the printed form and information identifying an electronic medical record that is personal to the patient; (col. 7, lines 6-10;col. 9, lines 32-49; col. 12, lines 53-62(identification may be kept personal); col. 13, lines 59-61)
- communicating the formatted data to an electronic medical record interface engine to automatically add the information to the patient's personal electronic medical record; and (Figure 4; col. 13, lines 6-25; 57-59; col. 14, lines 31-35, 58-67)

Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3), further comprising converting and formatting the obtained information into an appropriate format (col. 6, line 5-10; col. 7, lines 3-10; col. 9, lines 32-49), but does not expressly disclose the specific formats that are accommodated by the system. Johnson discloses a system/method for receiving and formatting data so that the data is in the form of an HL7 laboratory record (e.g. obtained from a patient record)(col. 7, lines 58-67). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Johnson to accommodate HL7 protocol standards for patient data, including lab records. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

Kraftson and Johnson disclose the method as described above. Kraftson further discloses presenting the patient's electronic medical record to the physician, including the information from the printed form, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (col. 13, lines 6-51—patient information in PDMA is gathered from MRS or E-PDS surveys) However, Kraftson and Johnson do not expressly disclose presenting the patient's personal electronic medical record to the physician during the patient's visit with the physician. Evans discloses a method/system wherein the physician may retrieve the patient's EMR during the patient's visit with the physician. (col. 5, lines 10-21—e.g. point-of-care system) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson and Johnson in combination with the teaching of Evans to allow the physician to retrieve the patient's EMR during the patient's visit. As suggested by Evans, one would have been motivated to include this feature to allow the physician to annotate the patient record with observations and comments made during an examination (col. 7, lines 34-40) .

Response to Arguments

12. Applicant's arguments filed 9/21/05 have been fully considered but they are not persuasive.

(A) Applicant argues that rejection of claims 7,13, and 15 under 112, 1st paragraph.

In response, the rejection of these claims has been withdrawn in light of the amendment filed 9/21/05.

(B) Applicant argues "Kraftson does not teach or suggest a method of allowing a patient to have limited input access to their electronic medical record including the step of 'sending the formatted data to an assigned location for importing into the patient's medical record...'"

In response to applicant's arguments, the recitation "allowing a patient to have limited input access to their electronic medical record" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Moreover, Kraftson does disclose "sending the formatted data to an assigned location for importing into the patient's medical record." (col. 6, lines 10-18; col. 7, lines 43-53; col. 9, lines 37-49; col. 13, lines 34-40) The information gathered from the patient survey is formatted as needed and incorporated into a patient record. While the survey records information regarding patient satisfaction, it also gathers information on the patient's medical conditions and treatments. (e.g. col. 9, lines 37-49; col. 13, lines 30-40)

Furthermore, claim 1 recites that the data gathered in the questionnaire may simply include "other pertinent information for answering by the patient." This broad language may encompass various types of data, and does not preclude patient satisfaction or patient opinion information. Also, the language of claim 1 does not positively recite that any information is actually imported into the patient's medical record. As it is currently worded, the data is merely sent or transmitted (to be processed/imported at some undetermined point in the future.) It is not clear from the current language whether or not the importation step is within the scope of the Applicant's invention.

(D) Applicant argues that a patient's EMR is "not a report containing results of an automated data analysis, but rather a private record containing that patient's personal medical information that is viewable at the time the patient receives care from the physician."

In response, it is respectfully submitted that the patient satisfaction data gathered by Kraftson is only one type of data gathered using the questionnaire forms. (See Figures 3A-3C) Moreover, it is respectfully submitted that a patient's satisfaction with treatments and treatment changes may reasonably interpreted as personal and private medical.

Furthermore, in response to applicant's argument that the Kraftson reference fails to show patient records or reports which are viewable at the time of care, it is noted that the features upon which applicant relies (i.e., patient records or reports which are

viewable *at the time of care*) are not recited in rejected claim(s) 1-8,9-12, 13-14, 17-19, and 21. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Only claim 20 recites the claimed limitation of accessing the record during the time of care. In this instance, a new combination of references has applied to address this limitation. It should be noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(E) Applicant traverses the Examiner's use of Official Notice in the rejections of claims 6-7 and 13-14.

In response, the Examiner noted that fact that "HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data." In other words these were established standards for the formatting and transmitting of data in the art.

MPEP 2144.03 states the following:

> To adequately traverse such a finding [a factual assertion], an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also Chevenard, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the

> examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained.

It is unclear to the Examiner which factual assertion the Applicant questions. However, as per Applicant's own admission in the Background of the Invention (page 10, lines 11-19) "...standards were developed to govern the format for data exchange between disparate computer systems. These standards are generically labeled as 'HL7' or Health Level 7, and govern the format for data exchange between scheduling, billing, medical records and laboratory systems."

The Examiner understands this to mean that HL7 is was an industry format standard at the time of the applicant's invention to facilitate the exchange of (medical) data among disparate computer systems. As to Applicant's assertion on pages 16-17 of the computer system HL7 is/was not adapted to receive information from a patient and to add information directly to the patient's medical record, it is respectfully submitted that the components of computer system or application would function the same regardless of the system operator (i.e. physician or patient). Moreover, Applicant's own description of HL7 indicates that the exchange of medical records (i.e. patient records) was possible at the time of the Applicant's invention using the industry standard HL7 format.

Similarly, Applicant's amendment to the Specification dated 9/21/05, indicates that ASTM provided other industry standard communication protocols, which could have been "used in a manner substantially similar to HL7 as described..." Applicant further

describes explains this as a modification that would have been recognized by one of ordinary skill in the art. (page 2 of 9/21/05 response)

Burks et al (USPN 5,644,778) further discloses the use of ANSI standard protocols for formatting and transmitting medical information among members a healthcare system. (col. 9, lines 52-67)

The Examiner respectfully submits that HL7, ANSI, and ASTM were well known in the art for establishing transmitting and formatting standards for data at the time of the Applicant's invention. As such, the Examiner's use of Official Notice was proper and the rejections of claims 6-7 and 13-14 are maintained.

(F) Applicant's arguments with respect to claims 18-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP

ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER